

Silver Spring, MD 20993-0002, 301-796-3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "FDA Oversight of PET Drug Products—Questions and Answers." In 1997, Congress passed the Food and Drug Administration Modernization Act (the Modernization Act) (Pub. L. 105-115). Section 121 of the Modernization Act directed FDA to establish appropriate approval procedures and current good manufacturing practices (CGMP) for PET drugs. The procedures were finalized and an implementation timeline was instituted on December 10, 2009, when FDA published regulations that described the minimum CGMP standards that each PET drug manufacturer is to follow during the production of a PET drug (see part 212 (21 CFR part 212)).¹ Under the requirements of section 121 of the Modernization Act, within 2 years following that publication date, a new drug application (NDA) or abbreviated new drug application (ANDA) must be submitted for any PET drug marketed for clinical use in the United States.

Recognizing that many PET drug producers are unfamiliar with the drug approval process, FDA issued the guidance entitled PET Drug Applications—Content and Format for NDAs and ANDAs,² and held a public meeting in March 2011 to assist applicants in preparing NDAs and ANDAs for the three most commonly used PET drugs. Numerous questions have been raised since that public meeting on all aspects of FDA oversight of PET drugs. This draft guidance is being issued to respond to the questions that have been submitted to date, and it will be revised periodically to respond to additional questions that have been submitted and are expected to be submitted in the future.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the FDA oversight of PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An

alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 were approved under OMB control numbers 0910-0001 and 0910-0338; the collections of information in 21 CFR part 312 were approved under OMB control number 0910-0014; the collections of information in part 212 were approved under OMB control number 0910-0667; the collections of information in 21 CFR parts 210 and 211 were approved under 0910-0139; and the collections of information in 21 CFR part 207 were approved under OMB control number 0910-0445. The draft guidance also refers to collections of information associated with submitting Form FDA 3397 (Prescription Drug User Fee Cover Sheet), approved under OMB control number 0910-0297.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4427 Filed 2-24-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0621]

Final Decision on Withdrawal of Breast Cancer Indication for AVASTIN (Bevacizumab) Following Public Hearing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final decision withdrawing approval of the breast cancer indication for AVASTIN (Bevacizumab). The Commissioner of Food and Drugs (the Commissioner) issued the decision following a June 2011 public hearing on a proposal to withdraw the approval.

DATES: Withdrawal of AVASTIN's breast cancer indication was effective November 18, 2011.

ADDRESSES: Submit written requests for single copies of the decision to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. The final decision, hearing transcript, and other documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1601, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the decision and related documents.

FOR FURTHER INFORMATION CONTACT:

Sharon Sickafuse, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2320.

SUPPLEMENTARY INFORMATION:

I. Background

On February 22, 2008, FDA's Center for Drug Evaluation and Research (CDER) approved a supplemental biologics license application (sBLA 125085/91) submitted by Genentech, Inc. (Genentech), for the use of AVASTIN in combination with paclitaxel for patients who have not received chemotherapy for treatment of HER2-negative metastatic breast cancer (MBC). This approval was issued under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E. Consistent with those regulations, the approval was

¹ The regulation, CGMP guidance, and supportive information, including historical documents, are available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm>.

² We update guidances periodically. To make sure you have the most recent version of a guidance, check FDA's Drugs guidance Web page at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

subject to the requirement that the product be studied further to verify and describe its clinical benefit. On November 16, 2009, Genentech submitted the results of two clinical trials intended to satisfy this requirement. CDER determined that these trials failed to verify AVASTIN's clinical benefit in the treatment of MBC and on December 16, 2010, issued a notice of opportunity for a hearing to Genentech proposing to withdraw approval of AVASTIN's MBC indication. Genentech submitted a hearing request dated December 23, 2010, followed by a submission of data and information on which it would rely at a hearing. The Agency granted Genentech's hearing request and published a notice of hearing on May 11, 2011 (76 FR 27332). The hearing was held on June 28 and 29, 2011. Following the hearing, on November 18, 2011, the Commissioner issued a final decision withdrawing approval of AVASTIN's MBC indication.

II. Electronic Access

Persons with access to the Internet may obtain the final decision at <http://www.fda.gov/downloads/NewsEvents/Newsroom/UCM280546.pdf>. The final decision, a transcript of the hearing, and other documents pertaining to the withdrawal of Avastin's MBC indication are available at <http://www.regulations.gov> under the docket number found in brackets in the heading of this document.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4424 Filed 2-24-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0605]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Institutional Review Board Continuing Review After Clinical Investigation Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval." The guidance

announced in this document finalizes the draft guidance of the same title dated January 2010. This document also supersedes the Information Sheet, Continuing Review After Study Approval. The guidance is intended to assist institutional review boards (IRBs) in carrying out their continuing review responsibility by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations.

DATES: Submit either electronic or written comments at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002 (1-888-463-6332 or 301-796-3400); or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448 (1-800-835-4709 or 301-827-1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993 (1-800-638-2041 or 301-796-7100). Send one self-addressed adhesive label to assist the office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Sara Goldkind, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. 301-796-8342.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval." This guidance is intended to assist IRBs in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding

the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review. This guidance supersedes the Information Sheet, "Continuing Review After Study Approval" (September 1998, Office of Health Affairs, Food and Drug Administration). To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts.

In the **Federal Register** of January 13, 2010 (75 FR 1790), FDA announced the availability of the draft guidance of the same title, dated January 2010. FDA received numerous comments on the draft guidance. All comments received during the comment period and questions received by Agency staff related to implementation of the regulations have been carefully reviewed and, where appropriate, incorporated into the guidance. Changes from the draft guidance include more detailed discussion about what should be submitted to assist the IRB in conducting continuing review, clarification of recommendations regarding submission of study-wide information for multi-site studies, discussion of the circumstances in which expedited review procedures may be used for continuing review, and revised guidance about how continuing review dates should be determined. In addition, FDA's draft guidance, "IRB Continuing Review after Clinical Investigation Approval", did not address IRB approval of research with conditions. Subsequent to OHRP's issuance of its guidance, "IRB Approval of Research with Conditions" (November 2010), FDA received multiple inquiries and comments recommending that FDA adopt the same policy. In response to these comments, FDA is including a discussion of IRB approval of research with conditions in the guidance.

This guidance is part of the Information Sheet Guidance Initiative, announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and